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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------|------------------|
| 10/088,202 | 03/15/2002 | Eun Jeong Park | 58049-00003 | 1462 |
| 7590 02/18/2005 | | | EXAMINER | |
| Joseph Hyosuk Kim | | | FORD, VANESSA L | |
| Squire Sanders & Dempsey 14th Floor 801 South Figueroa Street Los Angeles, CA 90017-5554 | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | TATER NOMBER |
| | | | DATE MAILED: 02/18/2005 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| | 10/088,202 | PARK ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Vanessa L. Ford | 1645 | | | | |
| The MAILING DATE of this communication Period for Reply | appears on the cover sheet wi | th the correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR RE THE MAILING DATE OF THIS COMMUNICATIO - Extensions of time may be available under the provisions of 37 CFI after SIX (6) MONTHS from the mailing date of this communication - If the period for reply specified above is less than thirty (30) days, a - If NO period for reply is specified above, the maximum statutory pe - Failure to reply within the set or extended period for reply will, by st Any reply received by the Office later than three months after the m earned patent term adjustment. See 37 CFR 1.704(b). | DN. R 1.136(a). In no event, however, may a relation. In reply within the statutory minimum of thirt iniod will apply and will expire SIX (6) MON pature, cause the application to become AB | eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 1 | <u>5 March 2002</u> . | | | | | |
| , | · · · · · · · · · · · · · · · · · · · | | | | | |
| 3) Since this application is in condition for allo | The state of the merits is | | | | | |
| Disposition of Claims | | | | | | |
| 4) ⊠ Claim(s) <u>1-20</u> is/are pending in the applicate 4a) Of the above claim(s) is/are with 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) ⊠ Claim(s) <u>1-20</u> are subject to restriction and | drawn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Exam | | | | | | |
| 10) The drawing(s) filed on is/are: a) | | | | | | |
| Applicant may not request that any objection to | | | | | | |
| Replacement drawing sheet(s) including the cor | | | | | | |
| Priority under 35 U.S.C. § 119 | | · · · · · · · · · · · · · · · · · · · | | | | |
| 12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of: 1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the papplication from the International But * See the attached detailed Office action for a | ents have been received. ents have been received in Appriority documents have been reau (PCT Rule 17.2(a)). | pplication No received in this National Stage | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | · · · · · · · · · · · · · · · · · · · | ummary (PTO-413))/Mail Date | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB. Paper No(s)/Mail Date | - · · · · · · · · · · · · · · · · · · · | formal Patent Application (PTO-152) | | | | |

Application/Control Number: 10/088,202

Art Unit: 1645

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Election/Restrictions

Group I Claims 1-2, 6, 14 and 18 are drawn to a detoxified protein.

Group II Claims 3-5, 7-9 and 15-17 and 19-20 are drawn to a DNA, vector and host cell.

Group III Claims 10 and 11 are drawn to a method of preparing a detoxified protein.

Group IV Claim 12 and 13 are drawn to a vaccine and mucosal adjuvant.

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2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a detoxified protein. The special technical feature lacks novelty under PCT Article 33(2) as anticipated by Domenighini et al, (EP 0 620 850 B1 published March 3, 1999). Domeninghini et al teach detoxified proteins of cholera toxins or heat labile toxins produced by *E. coli* which have a substitution at amino acid 63 (see the Abstract), Group I is the main invention in this application and it lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept. Inasmuch as, the technical feature does not define a contribution over the art, it is not "special" within the meaning of PCT Rule 13.2. Consequently, Groups I-IV lack unity of invention.

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Conclusion

3. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov./http://pair-direct.uspt

Vanessa L. Ford Biotechnology Patent Examiner February 10, 2005

> MARK NAVARRO PRIMARY EXAMINER